

### Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A method for treating a subject's tooth that needs regeneration of dentin, comprising,  
forming a hole in the tooth of the subject *in vivo*, the hole being of a depth sufficient to expose at least a portion of pulp;  
inserting a tissue scaffold into the hole so that a portion of the tissue scaffold contacts at least a portion of the exposed pulp; and  
regenerating dentin by allowing sufficient time for tissue to grow *in vivo*, from the pulp into the tissue scaffold, wherein that the tissue scaffold inserted into the hole does not include *ex vivo* cultured tissue.
2. (Canceled)
3. (Original) The method of claim 1 wherein the tissue scaffold is formed into a shape dimensioned to fit snugly into the hole that is formed so that the tissue scaffold does not move more than 0.1 mm in a lateral direction in the hole.
4. (Original) The method of claim 1 wherein the tissue scaffold is formed into a cylindrical wafer having a diameter of about 2 to about 5 mm and a height of about 0.1 to about 0.5 mm.
5. (Original) The method of claim 1 further comprising inserting dental stem cells into the hole between the exposed portion of the pulp and the tissue scaffold.
6. (Original) The method of claim 1 wherein the tissue scaffold is seeded with dental pulp stem cells prior to insertion into the hole.
7. (Original) The method of claim 1 wherein the tissue scaffold is comprised of calcium phosphate associated therewith.

8. (Original) The method of claim 7 wherein the tissue scaffold is comprised of fluoride associated therewith.
9. (Original) The method of claim 1 wherein the tissue scaffold is comprised of scaffolding material selected from the group consisting of PLLA, PDLLA, PGA and PLGA.
10. (Currently Amended) The method of claim 1 wherein the tissue scaffold is comprised of scaffolding material is PLGA.
11. (Original) The method of claim 1 wherein the tissue scaffold is further comprised of a physiologically effective amount of a morphogenic agent that promotes growth of dentin tissue.
12. (Original) The method of claim 11 wherein the morphogenic agent is encoded by a member of the TGF- $\beta$  supergene family.
13. (Currently Amended) The method of claim 11 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, VEGF, FGF-1, FGF-2, IGF-1, IGF-2, PDGF, GDF-1, GDF-2, ~~GDF-2~~, GDF-3, GDF-4, ~~And~~ and GDF-5.
14. (Currently Amended) The method of claim 11 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, ~~And~~ and GDF-5.
15. (Original) The method of claim 1 wherein the tissue scaffold is further comprised of an active agent selected from the group consisting of an anti-bacterial agent and an anti-inflammatory agent.

16. (Original) The method of claim 1 wherein the tissue scaffold has the shape of a cylindrical wafer having an upper surface, a downwardly extending cylindrical side, and a lower surface.

17. (Original) The method of claim 1 further including applying a barrier layer in contact with an exposed surface of the scaffold material to seal the scaffold material in the hole.

18. (Original) The method of claim 17 wherein the barrier layer is comprised of a hydrogel.

19. (Original) The method of claim 18 wherein the hydrogel comprises a physiologically effective amount of a morphogenic agent that promotes growth of dentin tissue.

20. (Original) The method of claim 18 wherein the barrier hydrogel comprises an active agent selected from the group consisting of an anti-bacterial agent and an anti-inflammatory agent.

21. (Currently Amended) The method of claim 18 wherein the morphogenic agent is encoded by a member of the TGF- $\beta$  supergene family.

22. (Currently Amended) The method of claim 18 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, VEGF, FGF-1, FGF-2, IGF-1, IGF-2, PDGF, GDF-1, GDF-2, ~~GDF-2~~, GDF-3, GDF-4, ~~And~~ and GDF-5.

23. (Currently Amended) The method of claim 18 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, ~~And~~ and GDF-5.

24. (Original) The method of claim 1 further including covering the hole with a cement or amalgam that contacts at least a portion of tooth enamel.

25. (Original) The method of claim 24 wherein the cement is comprised of di-calcium phosphate and tetra calcium phosphate.

26. (Original) The method of claim 24 wherein the cement is comprised of calcium phosphate and fluoride.

27. (Original) The method of claim 1 wherein the subject has asymptomatic caries and the act of forming the hole exposes a portion of the pulp located in the coronal pulp chamber.

28. (Currently Amended) The method of claim 1 wherein the subject has need of a root canal and the act forming the holes exposes a portion of the pulp between ~~in~~ at least one of the coronal pulp chamber and the root canal.

29. (Currently Amended) A device for treating a tooth comprising, a tissue scaffold comprised of a scaffolding polymer configured as a wafer that fits snugly into a corresponding hole that is formed in a tooth of the subject so that the tissue scaffold does not move more than 0.1 mm in a lateral direction in the hole, wherein the tissue scaffold does not include *ex vivo* cultured tissue.

30. (Original) The device of claim 29 wherein the hole of corresponding size is formed by an act of drilling the tooth.

31. (Currently amended) The ~~method~~ device of claim 29 wherein the wafer is cylindrical and has a diameter of about 2 to about 5 mm and a has height of about 2 to about 4 mm.

32. (Original) The device of claim 29 wherein the scaffolding polymer is made of a material selected from the group consisting of PLLA, PDLA, PGA and PLGA.

33. (Original) The device of claim 29 wherein the scaffolding material is associated with calcium phosphate.

34. (Original) The device of claim 33 wherein the wafer is further associated with fluoride.

35. (Original) The device of claim 29 further comprising a pharmaceutically acceptable hydrating liquid.

36. (Original) The device of claim 29 wherein the wafer has a top surface, a bottom surface and a side perimeter surface between the top and bottom surfaces, and wherein at least one of the top and bottom surfaces are marked with a pattern that alters appearance when the wafer is crushed.

37. (Original) The device of claim 36 wherein the pattern is comprised of set of concentric circles.

38. (Original) The device of claim 36 wherein the pattern is comprised of a dye that alters color when the wafer is compressed.

39. (Original) A kit containing a plurality of wafers according to claim 29 and wherein the plurality of wafers are of a plurality of sizes selected to correspond with a plurality of hole sizes.

40. (Original) The kit of claim 39 wherein the plurality of hole sizes correspond to a plurality of holes made by drilling a tooth with any one of a plurality of dental drill bit sizes.

41. (Original) A composition for treating dental tissue, comprising a tissue scaffold wafer comprising a scaffolding material associated with calcium phosphate and fluoride.

42. (Original) The composition of claim 41 further comprising a physiologically effective amount of a morphogenic agent that promotes growth of dentin tissue.

43. (Currently amended) The ~~method~~ composition of claim 42 wherein the morphogenic agent is encoded by a member of the TGF- $\beta$  supergene family.

44. (Currently amended) The ~~method~~ composition of claim 42 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, VEGF, FGF-1, FGF-2, IGF-1, IGF-2, PDGF, GDF-1, GDF-2, ~~GDF-2~~, GDF-3, GDF-4, ~~And~~ and GDF-5.

45. (Currently amended) The ~~method~~ composition of claim 42 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, ~~And~~ and GDF-5.

46. (Original) The composition of claim 41 further comprising an active agent selected from the group consisting of an anti-bacterial agent and an anti-inflammatory agent.

47. (Canceled)

48. (Original) The composition of claim 41 wherein the tissue scaffold is comprised of scaffolding polymer selected from the group consisting of PLLA, PDLLA, PGA and PLGA.

49. (Original) The composition of claim 41 wherein the tissue scaffold is comprised of PLGA.

50. (Currently amended) A kit for providing a method of treating dental conditions, comprising:

a dry tissue scaffold wafer dimensioned to be received into a hole of corresponding size formed in a tooth of a subject;

a well configured to hold the tissue scaffold wafer in a dry state,  
a second well adjacent to the first well, the second well holding a hydrating liquid comprising a pharmaceutically acceptable liquid; and

a breakable partition separating the first and second wells, the breakable partition being structured to break by a force applied by a human hand causing the tissue scaffold wafer to contact hydrating liquid when the breakable partition is broken.

51. (Original) The kit of claim 50 wherein a plurality of the first wells are configured with a plurality of second wells, each member of the plurality of first and second wells having the breakable partition between the wells.

52. (Currently Amended) The kit of claim 51 wherein the plurality of first wells is dimensioned to hold a plurality of dry wafers of different sizes.

53. (Original) The kit of claim 50, further comprising a hydrogel material.

54. (Original) The kit of claim 53 wherein the hydrogel is hydrated, contained in a well in the kit, and has a size that corresponds to a size of the tissue scaffold wafer.

55. (Original) The kit of claim 54 including a plurality of hydrogels.

56. (Original) The kit of claim 53 wherein the hydrogel material is provided in a dry state in the kit.

57. (Original) The kit of claim 56 further comprising a hydrating liquid for hydrating the dry hydrogel material.

58. (Original) The kit of claim 56 wherein at least one of the dry tissue scaffold or the hydrating agent or a hydrogel optionally included with the kit, contains a morphogenic agent.

59. (Original) The kit of claim 58 wherein the morphogenic agent is encoded by a member of the TGF- $\beta$  supergene family.

60. (Currently amended) The ~~method~~ kit of claim 58 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, VEGF, FGF-1, FGF-2, IGF-1, IGF-2, PDGF, GDF-1, GDF-2, ~~GDF-2~~, GDF-3, GDF-4, ~~And~~ and GDF-5.

61. (Currently amended) The ~~method~~ kit of claim 58 wherein the morphogenic agent is selected from the group consisting of BMP-2, BMP 4, BMP-7, ~~And~~ and GDF-5. ~~The kit of claim 48 wherein the morphogenic agent is supplied with the dry tissue scaffold wafer.~~

62. (Original) The kit of claim 58 wherein the morphogenic agent is supplied with the hydrating liquid.

63. (Original) The kit of claim 58 wherein the morphogenic agent is supplied with the hydrogel.

64. (Original) A device for supporting a tissue scaffold wafer comprising, a support casing at least partially surrounding the tissue scaffold wafer, the tissue scaffold wafer being made of a porous scaffolding material having a first crushing resistance and the support casing being made of a material having a second crushing resistance greater than the first crushing resistance.

65. (Original) The device of claim 64 wherein the support casing includes at least one horizontally disposed member that contacts at least one of an upper and lower surface of the tissue scaffold wafer and wherein the support casing includes at least one



columnar extension extending from the horizontally disposed member along a side perimeter of the tissue scaffold wafer.

66. (Original) The device of claim 65 wherein the horizontally disposed member of the support casing includes at least one ring that contacts an outer perimeter of at least one of an upper and lower surface of the tissue scaffold wafer.

67. (Original) The device of claim 65 wherein the horizontally disposed member includes a bracket member.

68. (Original) The device of claim 65 wherein the horizontally disposed member includes a pad member.

69. (Original) The device of claim 65 wherein the horizontally disposed member includes a brace member.

70. (Original) The device of claim 64 wherein the support casing includes a plurality of the columnar extensions of the support material.

71. (Original) The device of claim 64 wherein the support casing is biodegradable in a mouth of an animal.

72. (Currently amended) A vacuum manipulator for manipulating a tissue scaffold wafer, comprising:

a vacuum tube having a proximal end, a distal end, and walls between the proximal and distal ends enclosing the vacuum tube;

an attachment ~~for a vacuum source in~~ at the distal end of the vacuum tube to permit fluid communication between a vacuum source and with the vacuum tube;

a suction cup attached to the proximal end of the vacuum tube in fluid communication with the vacuum tube, the suction cup being sized to fit onto a surface of a wafer comprised of dental scaffolding material; and ~~and~~

a valve assembly ~~at the distal end of the vacuum tube~~ positioned at the distal end of the vacuum tube proximate to the vacuum source, the valve assembly being operable to close and open fluid access between the vacuum tube and a vacuum source and to open and close fluid access between the vacuum tube and a pressure source.

73. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 wherein the valve assembly is manipulated by a manual dial.

74. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 further including an in-line filter disposed in the vacuum tube between the suction cup and the distal end, the in-line filter having sufficient pore volume to allow passage of the fluid between the suction cup and the vacuum tube while preventing the passage of a pathogen.

75. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 wherein the vacuum tube has a bend along the length thereof to orient the proximal end for insertion into a mouth of human along a plane defined by crowns of teeth;

76. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 wherein the vacuum source is comprised of a pliable bulb shaped member.

77. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 wherein the attachment for the vacuum source is comprised of a hose attachable to an external vacuum source.

78. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 further comprising a source of positive pressure in fluid communication with the vacuum tube through the vacuum assembly.

79. (Original) The vacuum manipulator of claim 78 wherein the positive pressure source is ambient air pressure.

80. (Original) The vacuum manipulator of claim 78 wherein the pressure source is a source of positive air flow that is greater than ambient air pressure.

81. (Currently amended) The vacuum manipulator of claim ~~77~~ 72 wherein the valve assembly is adjustable to allow a controlled amount of at least one of positive or negative pressure to be drawn or applied within the vacuum tube.

82. (New) The kit of claim 58 wherein the morphogenic agent is supplied with the dry tissue scaffold water.